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UNCLAS SECTION 01 OF 03 ANKARA 002071

SIPDIS

DEPT FOR EB/TPP/MTA/IPC - SWILSON/JURBAN AND EUR/SE
DEPT PASS USTR FOR LERRION/BPECK
DEPT PASS LIBRARY OF CONGRESS
DEPT PASS USPTO FOR ELAINE WU
USDOC FOR ITA/MAC/DDEFALCO

SENSITIVE

E.O. 12958: N/A
TAGS: ETRD KIPR TU
SUBJECT: Pharmaceuticals Update: GOT's Unsatisfactory Data Exclusivity Proposal, Revised Pricing Decree

Ref: Ankara 1157 and previous

Summary

¶1. (SBU) The Health Ministry has proposed a data exclusivity strategy predicated on implementation at the end of 2007, and with an effective term of less than three years. The research-based pharmaceutical industry is reacting very negatively, and the Embassy has again weighed in on this issue. The Ministry is revising its decree on drug pricing in ways that are, on balance, likely to make its implementation less painful for U.S. companies. Embassy recommends increased Washington pressure on the GOT on data exclusivity. End Summary.

Limited Data Exclusivity in 2007

¶2. (U) On March 31, the Health Ministry proposed a strategy (translation at end of cable) on data exclusivity which calls for implementation on December 31, 2007. Although the term of exclusivity (and patent protection) is to be six years, it would in fact be less than half of that, as no drug could be registered in Turkey until three years had elapsed from registration in a foreign country, with the term of exclusivity beginning from that earlier date. The term of protection would be further shortened by the period required for registration procedures in Turkey. The Ministry asked that the Association of Research-Based Pharmaceutical Companies (AIFD) comment on this by April ¶9.

¶3. (SBU) Not surprisingly, AIFD members have sharply criticized the GOT proposal as inadequate. Chris Kartalis, the General Manager of Bristol-Myers Squibb Turkey, told Econoff that AIFD would send a strong response to the Ministry before the deadline. Additionally, former Secretary Albright, who is visiting Ankara in connection with an invitation from research-based industry, is likely to raise the issue in a meeting with the Health Minister on April 9.

¶4. (SBU) Acting DCM raised the Ministry strategy in an April 7 meeting with Undersecretary Unuvar. A/DCM maintained that swift implementation of data exclusivity protection was essential to building a strong investment climate in Turkey. Unuvar refused to comment in any detail on the strategy, maintaining that the implementation date and other provisions were subject to the approval of other GOT agencies. He raised the generic industry's exaggerated estimates of the budgetary cost of data exclusivity as a factor in the GOT's deliberations on this issue.

Limited Progress on Pricing Decree

¶5. (SBU) Following intense AIFD lobbying and Commerce U/S Aldonas' letter on the GOT's new reference pricing system, the Health Ministry is revising it in ways that should make it less painful for research-based industry. U/S Unuvar confirmed that, instead of limiting pharmaceuticals prices to a maximum of 90 percent of the

average of the lowest two prices prevailing in a group of five European countries, 100 percent of the lowest price in these five countries will be used as a reference. While industry sources tell us this is an improvement, several companies say this revised system will still be painful and unfair because Turkey will not permit upward price adjustment if the minimum price in Europe is higher than the previous Turkish maximum. AIFD advises that it may pursue a legal challenge to the new price decree when it is issued (protect).

Comment

¶6. (SBU) Although the data exclusivity scheme proposed on March 31 may be amended, Embassy believes that the GOT is not likely to implement a satisfactory data exclusivity policy without significantly increased external pressure and engagement. We have proposed, by diplomatic note, an expert-level bilateral discussion of intellectual property issues via digital video conference to the MFA. USTR is due to issue its Special 301 report at the end of April. As recommended reftels, further Washington engagement would buttress these steps. In particular, Washington agencies should rebut Turkey's argument that the TRIPS Agreement does not require data exclusivity and provide an analysis of any other areas in which we believe that the GOT is not fulfilling its TRIPS obligations, as promised after the December 2003 Economic Partnership Commission meeting. We continue to believe that sending an interagency IPR delegation to Ankara would have more impact on GOT decisionmaking than a discussion by DVC.

¶7. (U) Begin Text AIFD Translation of Health Ministry Letter:

THE MINISTRY OF HEALTH
OF THE TURKISH REPUBLIC
The Pharmaceutical General Directorate
NO : B100IEG0100007/014283
ISSUE :
ANKARA
March 31,2004

THE ASSOCIATION OF RESEARCH-BASED
PHARMACEUTICAL COMPANIES
Barbaros Bulvary No:85/A D:4
Besiktas/ISTANBUL

As you may know, the "National Programme of Turkey for the Adoption of the European Union Acquis Communautaire", had been published on the Reiterated Official Gazette dated July 24, 2003, no. 25178.

As a result of the works conducted within the framework of the "Directive 2001/83/EC of the European Parliament and of the Council, of November 6, 2001, relating to medicinal products for human use", anticipated to be harmonised according to the National Programme, it has been deemed necessary to revoke the Regulation on the Registration of Medicinal Pharmaceutical Products, published on the Official Gazette no. 22218, dated March 02, 1995 and draw up a new Regulation in line with the section about market introduction of above mentioned directive.

The following issues are planned to be reflected in the Regulation Regarding the Registration of Medicinal Products for Human Use which is being drawn up:
Any medicinal product for human use, including blood products, vaccines and radiopharmaceuticals:
¶1. will be registered earliest three years after its first registration in the EU, the United States or any other country,
¶2. the implementation of data exclusivity in our country will be initiated as of December 31, 2007,
¶3. the implementation of data exclusivity and patent period will be limited for 6 years in our country, as of the first registration date of the product in the EU, the United States or any other country,
¶4. an additional period of 1 year will be implemented in the event of the addition of a new indication, by condition that such period is limited by the patent period in our country,
¶5. the targeted completion of the registration procedure

within 210 working days will be implemented upon the institutionalization of our General Directorate; in other words, it will be implemented after the establishment of the National Pharmaceutical Institution and a transition period will be foreseen to allow an improvement of the physical structure until such an institutional structuring takes place,

¶6. in the event of the change of the registration holder and the positive evaluation of the application submitted with the document required by the related legislation, with the exemption of the scientific and technological inspections and laboratory analyses, a registration will be drawn up in the name of the new applicant but the company of origin will be prevented from transferring the import registration unilaterally to another company, before the completion of 5 years,

Furthermore,

¶7. the implementation of the procedure for granting registration/permission to Homeopathic Products in our country will be initiated as of the EU candidacy date of Turkey.

We would highly appreciate if you could submit your comments about the following issues to the General Directorate by April 9, 2004.

Pharm. Hayriye MIHCAK
General Director
End Text AIFD Translation of Health Ministry Letter.
Edelman